REMARKS

This is in response to the Office Action mailed on February 5, 2008. With this Amendment, claims 2 and 6 are canceled without prejudice or disclaimer, and claims 1 and 5 are amended. All amendments are fully supported by the specification and drawings. No new matter is added. Claims 7-8 were previously canceled, such that claims 1-5 are pending in this application. In light of the foregoing amendments and following remarks, Applicant respectfully requests advancement of this application to allowance.

Amendments to the Abstract

The abstract has been amended. A separate sheet containing an unmarked version of the amended abstract is provided at page 9 of this paper. No new matter is added.

Claim Rejection – 35 U.S.C. § 102(b)

Claim 1 was rejected as being anticipated by Koestner et al. (U.S. Patent No. 5,139,020). No explanation was provided in the Office Action as to how Koestner anticipates claim 1. The rejection is respectfully traversed and the sufficiency of the rejection is not conceded. However, in an effort to advance this application to allowance, claim 1 is amended.

Claim 1 is directed to a method of tuning a cardiac prosthetic pacing device. The method recites, in part, "monitoring the flow output from the heart utilizing a transcutaneous continuous wave Doppler signal directed at the heart to obtain a signal indicative of intra-cardiac blood flow velocity."

Koestner fails to disclose each element of claim 1. The Koestner device uses an invasive technique that involves the implanting of ultrasound transducers in one of the right chambers of the heart (e.g., FIG. 7). The Examiner acknowledges that "Koestner et al. do not utilize a transcutaneous CW Doppler signal and thus do not disclose monitoring means that are noninvasive." Page 4.

Koestner notes in the background that non-invasive Doppler ultrasound techniques are known. The non-invasive technique noted by Koestner involve "measure[ment of] the maximum blood flow velocity in the aorta or pulmonary artery." Col. 5, lines 31-36. Thus, even the discussion of the non-invasive technique in Koestner fails to disclose a transcutaneous signal

"directed at the heart" and used to "obtain a signal indicative of intra-cardiac blood flow velocity," as recited in claim 1.

Reconsideration and withdrawal of the rejection of claim 1 is therefore requested.

Claim Rejections – 35 U.S.C. § 102/103

Claims 3 and 4 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Koestner et al. Claims 2, 5, and 6 were rejected under 35 U.S.C. § 103(a) as being obvious over Koestner et al. The rejections are respectfully traversed. However, in an effort to advance this application to allowance, claims 2 and 6 are canceled without prejudice or disclaimer and claim 5 is amended.

Claims 3 and 4 depend from claim 1, and are allowable for at least the reasons discussed above. Reconsideration and withdrawal of the rejection of claims 3 and 4 is requested.

Claim 5 is directed to an apparatus for tuning a cardiac prosthetic pacing device. The claim recites, in part, "monitoring means for using transcutaneous continuous wave Doppler directed at the heart to obtain a signal indicative of intra-cardiac blood flow velocity."

Koestner fails to disclose or suggest each element of claim 5. The Koestner device uses an invasive technique that involves the implanting of ultrasound transducers in one of the right chambers of the heart (e.g., FIG. 7). The Examiner acknowledges that "Koestner et al. do not utilize a transcutaneous CW Doppler signal and thus do not disclose monitoring means that are noninvasive." Page 4.

Koestner notes in the background, however, that non-invasive Doppler ultrasound techniques are known. The non-invasive technique noted by Koestner involves "measure[ment of] the maximum blood flow velocity in the aorta or pulmonary artery." Col. 5, lines 31-36. Thus, the technique described is not "directed at the heart" and does not "obtain a signal indicative of intra-cardiac blood flow velocity," as recited in claim 5.

Further, the Office Action suggests that it would have been obvious to modify the system of Koestner with the prior art non-invasive technique. Applicant respectfully disagrees. In fact, Koestner teaches away from such a combination by disclosing that non-invasive techniques have been used, but then proceeding to describe only an invasive technique. Further, Koestner notes

that prior techniques have been inaccurate and complex due to "lack of access to direct measurements within the left ventricle." Col. 5, lines 26-30.

At best, Koestner recognizes the difficulties in obtaining an accurate measurement for cardiac output by known transcutaneous techniques involving insonation of the aorta or pulmonary artery (e.g., as discussed in column 5, lines 31 to 44). These difficulties arise, at least in part, due to the presence of offshoots from the aorta or pulmonary artery and from the elasticity of the walls of those vessels.

In particular, the ascending aorta has many arterial offshoots which distribute blood to the upper extremities, such as the heart itself and the brain. Where an arterial offshoot upstream of the point at which blood flow velocity is measured supplies blood to a system at which the load changes, for example as a result of trauma, the flow velocity at the measurement zone may change. Thus, flow volumes may vary considerably within the ascending aorta in ways which are not in fact related to cardiac function, such that the measured flow rates are not truly indicative of cardiac output.

Furthermore, in addition to the existence of offshoots, the ascending aorta is elastic and its diameter changes during the cardiac cycle by as much as 20% (resulting in a change in cross-sectional area of around 45%). A change in the blood pressure of a patient may change the extent to which the diameter of the ascending aorta changes to accommodate blood flow. Thus, there is a physiological phenomenon (the change in aortic cross-section) which may affect the flow velocity but which is not itself measured. Indeed, Koestner indicates that the cross-sectional area of the vessel being insonated is "estimated." Thus, the velocity measured by the methods referred to by Koestner is only an approximation of the true velocity. Moreover, the flow rate calculated as a function of velocity and cross-sectional area multiplies the inaccuracies of the two parameters.

In addition to Koestner not disclosing each element of claim 5, it further would not have been obvious to modify Koestner in the manner recited in claim 5. There would not have been, as the Office Action suggests at page 4, "a reasonable expectation that tuning a pacer with a noninvasive Doppler monitoring means would have met with success" for at least those reasons noted above.

Reconsideration and withdrawal of the rejection of claim 5 is therefore requested.

CONCLUSION

In view of the above Amendment and Response, Applicant respectfully requests a Notice of Allowance. There may be additional reasons that the pending subject matter is patentably distinct from the cited references in addition to those discussed herein. Applicant reserves the right to raise any such arguments in the future. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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